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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,332	03/22/2007	Ines Batinic-Haberle	5405-374	5716

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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,332	BATINIC-HABERLE ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4* is/are allowed.

6)☒ Claim(s) *5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group IV in the reply filed on February 24, 2009 is acknowledged.

Groups I-III are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement, and reserved the right to file a divisional application to the non-elected subject matter.

An action on the merits on claims 1-14 is contained herein.

Information Disclosure Statement

Receipt of the information disclosure statement filed August 3, 2006 is acknowledged, and a copy is enclosed herewith.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

1. Claims 5-14 are directed to a method of protecting cells from oxidant-induced toxicity, and treating pathological conditions resulting from oxidant-induced toxicity and

degradation of NO, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease. The terms are interpreted to include any and all forms of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease. In re Hokum, 226 USPQ 353 (ComrPats 1985).

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for treating cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease are treated. Thus, the claims are extremely broad.

The nature of the invention

The nature of the invention is the treatment of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease through the use of the claimed compound and derivatives thereof. Currently, there are no known agents that protect cells and treat these diseases all inclusively. It is also reported that there are no known agents that treat tumors and cancers all inclusively. (See Pinedo et al. pages 1-2).

The level of predictability in the art

The treatment of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease is highly unpredictable. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Additionally, in the case of treating cancer, the treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential

for metastases, the fact that cancer therapeutics is palliative rather than curative and that cancer treatment readily harms normal tissues. (See McMahon, page 5, col. 2).

The amount of direction provided by the inventor.

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease claimed. Further, the applicant discloses that an effective amount of the compound will be administered without providing any direction other than that the compounds of the invention have a high therapeutic index and follows this with a definition readily found in a basic pharmacology textbook. It should be noted that the therapeutic index of a drug in humans is almost never known and is only determined through clinical experience.

The existence of working examples.

There is not seen in the disclosure, sufficient evidence to support Applicant's claims of treating cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The

disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment and methods of protecting cells. There are not sufficient working examples or data from references of the prior art to provide a nexus between those examples and a method of treating cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease with the claimed compound.

The level of one of ordinary skill.

The level of skill is that of one with a doctoral understanding of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease therapeutics. Applicant's data is not convincing as to make the production and use of pharmaceutical compositions comprising the recited compounds feasible without undue, un-predictable experimentation.

The quantity of experimentation.

A great deal of experimentation is required. In order for there to be a method of treating cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary

skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of cells, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease with the claimed compound individually or in combination with other therapeutic agents.

Further, a great deal of experimentation is required to treat cancer. In order for there to be a method of treating solid tumors and cancer generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of cancers can be treated that have differing cell types, locations and potentials for metastases. Furthermore, direction, in the form of examples, must be shown to determine what an effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat the multitudes of different types of tumors and cancer with the claimed compound individually or in combination with other therapeutic agents.

Thus, it can be safely concluded that the instant case fails to provide an enabling disclosure for protecting cells from oxidant-induced toxicity, and treating pathological conditions resulting from oxidant-induced toxicity and degradation of NO, inflammatory lung disease, neurodegenerative conditions, radiation injuries, cancer, diabetes, cardiac conditions and sickle cell disease.

Allowable Subject Matter

Claims 1-4 (compounds of elected Group IV) are in condition for allowance except for the presence of non-elected subject matter in the claims. The compounds in Claims 1-4 were not found to be obvious nor anticipated by the prior art of record. The closest prior art, US Patents 6,479,477 and 5544,975 (Crapo et al.) and Hunt et al. (Chemistry and Biology'1997), contains substituted porphyrin compounds substituted with other moieties and 6-membered heterocyclic rings, which differs from the instantly claimed porphyrin compounds containing a 5-membered heterocyclic ring with two nitrogens within the 5-membered heterocyclic ring. Thus, the prior art does not teach or suggest the presently claimed compounds. Therefore, these claims are in condition for allowance except for the presence of non-elected subject matter in the claims.

Conclusion

Claims 1-14 are pending. Claims 5-14 are rejected. Claims 1-4 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V. WARD whose telephone number is (571)272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/PAUL V WARD/

Examiner, Art Unit 1624